GENEXA ACETAMINOPHEN PM EXTRA STRENGTH- acetaminophen tablet, coated
Genexa Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Acetaminophen PM Extra Strength Caplets

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Nighttime sleep aid

Uses

temporarily relieves occasional headaches and minor aches and pains with accompanying sleeplessness

Warnings

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take
- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:
- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on the skin
- in children under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product
- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

• do not take more than directed (see Overdose warning)

adults and children 12 years and over
- take 2 caplets at bedtime if needed
- do not take more than 2 caplets in 24 hours, unless directed by a doctor

children under 12 years

ask a doctor

Other information
- each caplet contains: **calcium 65 mg, sodium 9 mg**
- store between 20-25°C (68-77°F)

Inactive ingredients

acacia gum‡, agave fiber‡, agave syrup‡, calcium carbonate‡, organic carnauba wax, cellulose‡, dextrose‡, dibehenin (vegetable source)‡, glycerin‡, guar gum‡, maltodextrin‡, organic palm olein, rice extract‡, rice hulls‡, sodium bicarbonate‡, organic sunflower lecithin, sunflower oil‡

‡natural

***Questions?* 1-855-436-3921**

Carton and bottle are safety sealed. DO NOT use if seal on top and/or bottom of carton or under cap of bottle is disturbed or missing.

*This product is not manufactured or distributed by Johnson & Johnson Corp., owner of the registered trademark Tylenol® PM Extra Strength Caplets.

Patent Pending | Distributed by: Genexa Inc.

Atlanta, GA 30318 | genexa.com

Made in the USA with globally sourced ingredients

NDC 69676-0063-2

R-20220310

Genexa®

MEDICINE MADE CLEAN

For Adults

Acetaminophen **PM Extra Strength**

with Diphenhydramine HCl

Pain Reliever Nighttime Sleep Aid

Compare to active ingredients in **Tylenol® PM Extra Strength Caplets***

100 Caplets

Non-habit forming

How we're different

Made without: crospovidone, polyethylene glycol, titanium dioxide **& more!**

GENEXA ACETAMINOPHEN PM EXTRA STRENGTH

acetaminophen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69676-0063
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
RICE BRAN (UNII: R60QEP13IC)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
INULIN (UNII: JOS53KRJ01)	
PALM OIL (UNII: 5QUO05548Z)	
ACACIA (UNII: 5C5403N26O)	
AGAVE TEQUILANA JUICE (UNII: GVG8G0207O)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DEXTROSE (UNII: IY9XDZ35W2)	
GUAR GUM (UNII: E89I1637KE)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	white (LIGHT BEIGE WITH SPECKLES)	**Score**	no score
Shape	OVAL (Oblong)	**Size**	18mm
Flavor		**Imprint Code**	G7
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69676-0063-2	1 in 1 CARTON	02/17/2022	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69676-0063-5	1 in 1 CARTON	02/17/2022	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part343	02/17/2022	

Labeler - Genexa Inc. (079751024)

Revised: 5/2022 Genexa Inc.